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D. D. N. J., F. D. C. 326-425

Issued March 1942

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

326-425

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. McNUTT, *Administrator, Federal Security Agency.*

Washington, D. C., January 15, 1942.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

326. Misbranding of Pachanga Mineral Water. U. S. v. Tripo M. Lukovich, trading as T. M. Lukovich, D. C. Plea of guilty. Fine of \$100 on count I. Imposition of sentence suspended on count II and defendant placed on probation for 2 years. (F. D. C. No. 2956. Sample Nos. 31518-E, 31532-E.)

This product contained excessive fluorine and would be dangerous to health when used as directed in the labeling. Its labeling failed to reveal the fact that it contained fluorine and failed to bear adequate warnings against use by children. The labeling of one lot contained false and misleading representations regarding its efficacy in certain ailments and conditions and failed to bear an accurate statement of the quantity of the contents.

On April 24, 1941, the United States attorney for the Southern District of California filed an information against Tripo M. Lukovich, trading as Dr. T. M. Lukovich, D. C., Elsinore, Calif., alleging shipment on or about September 5 and November 25, 1940, from the State of California into the State of Michigan of quantities of Pachanga Mineral Water that was misbranded.

Analysis showed that the article consisted essentially of sodium chloride, sodium sulfate, sodium bicarbonate, sodium carbonate, a fluorine compound, and a trace of an iron compound, dissolved in water. The total amount of dissolved matter was 2 percent. Samples taken from the two shipments were found to contain 52.2 and 60 parts, respectively, per million of fluorine.

The product in both shipments was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, and suggested in the labeling, namely, (one shipment) "Directions: From $\frac{1}{2}$ to $\frac{3}{4}$ of an ordinary glass before breakfast and before retiring"; (second shipment) "Natural Water," since it contained an excessive amount of fluorine.

Both lots were alleged to be misbranded further in that the labeling was misleading since it failed to reveal the fact that the article contained fluorine, a poisonous substance, which fact is material in the light of the representations made in the labeling and material with respect to consequences which might result from the use of the article under the conditions of use prescribed in the labeling and under such conditions of use as are customary or usual.

Both lots were alleged to be misbranded further in that the labeling did not bear adequate warnings against use by children, where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. The shipment of September 5, 1940, was alleged to be misbranded further in that the following statements in the labeling, "Try Pachanga Water for the Relief of certain ailments of Stomach, Bowels, Liver, Kidney, etc." and "Chemical Analysis show that Pachanga Water contains many mineral ingredients in a combination which has proven remarkably beneficial for many ailments of the human system," borne on the bottle label, were false and misleading since the article would not be efficacious and beneficial in the treatment of such ailments. This shipment was alleged to be misbranded further in that the bottle label failed to bear an accurate statement of the quantity of the contents.

On May 26, 1941, a plea of guilty having been entered, the court imposed a fine of \$100 on count I and ordered that imposition of sentence be suspended on count II and that the defendant be placed on probation for 2 years.

327. Misbranding of Pachanga Mineral Water. U. S. v. 59 Bottles of Pachanga Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 3568. Sample No. 31532-E.)

This product contained fluorine. It would be dangerous to health when used as directed in the labeling, and it was not labeled to indicate the consequences that might result from its use.

On December 21, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 59 bottles of Pachanga Mineral Water at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about November 25, 1940, by Dr. T. M. Lukovich from Elsinore, Calif.: and charging that it was misbranded. It was labeled in part: "Pachanga Mineral-Antacid-Laxative Natural Water Pachanga Mineral Well."

The article was alleged to be misbranded in that the statement "Mineral-Antacid-Laxative Natural Water" was false and misleading since the label failed to reveal the fact that the article contained fluorine, a poisonous substance.

It was alleged to be misbranded further in that the label failed to bear adequate warnings against use by children where its use might be dangerous to health and against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling "Natural Water."

On January 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

328. Misbranding of Aspirol Tablets and headache tablets. U. S. v. 1,005 Bottles of Aspirol Tablets and 1,416 Bottles of Headache Tablets. Consent decree of condemnation. Aspirol Tablets ordered released under bond for re-labeling; headache tablets ordered destroyed. (F. D. C. Nos. 2222, 2223. Sample Nos. 15165-E, 15169-E.)

The product Aspirol Tablets was labeled to indicate that it was an aspirin preparation; whereas it contained other physiologically active ingredients. Its label also failed to bear a statement of the quantity of acetophenetidin that it